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UCRL-AM-210386

Condition Reporting and Resolution

Quality Implementing Procedure ID: OSTI-LLNL-QIP-16.0, Rev.0, Mod.0

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March 10, 2005

This work was performed under the auspices of the U.S. Department of Energy by University of California, Lawrence Livermore National Laboratory under Contract W-7405-Eng-48.

CONDITION REPORTING AND RESOLUTION

Quality Implementing Procedure ID: OSTI-LLNL-QIP-16.0, Rev. 0, Mod. 0 *Effective:* 2/25/05

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and process to ensure that Conditions Adverse to Quality (CAQs) identified on the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project activities, including those conditions considered significant, are promptly identified and corrected as soon as practical. This procedure also establishes the responsibilities and process for the Quality Assurance (QA) Manager to issue a Stop Work Order, and the requirements for trending CAQs.

2. SCOPE

This procedure applies to all individuals within the OSTI-LLNL Project who identify, investigate, evaluate, correct, or verify corrective action for a CAQ and any Stop Work Order associated with OSTI-LLNL activities subject to the OSTI-LLNL Quality Assurance Plan (QAP) which implements the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. A CAQ shall be identified when a QAP requirement or an implementing document requirement is not met. Conditions that represent nonconforming products, data or samples are managed in accordance with OSTI-LLNL-QIP-15.0, *Nonconformances*.

3. PROCEDURE

All timeline requirements or due dates identified in this procedure are associated with the administrative management of the corrective action process. Failure to meet these dates and subsequent management actions are not CAQs but are part of the overall management of the process to ensure timely resolution of CAQs.

3.1 IDENTIFYING AND DOCUMENTING A CONDITION ADVERSE TO QUALITY (CAQ)

A CAQ is a state of noncompliance with OSTI-LLNL QA Program requirements. Any OSTI-LLNL staff member can initiate a CAQ when a deficient condition is discovered.

3.1.1 Initiator:

A. Document the CAQ by completing Blocks 2 through 8 of the Condition Report (CR) (Attachment 1) using the instructions provided. Use the CR Continuation Page (Attachment 2), if necessary.

B. Review the CR with the responsible Principal Investigator (PI) or Responsible Individual associated with the CAQ as identified in Block 4 of the CR. The Initiator, working with the PI is responsible for the technical aspects of the CR.

C. Obtain the PI or Responsible Individual signature and date (Block 9) for a condition corrected during an activity that is considered to be an isolated condition with no further extent of condition warranted (i.e., Block 7a is checked). Submit the CR to the QA Manager for review.

3.1.2 QA Manager (or designee):

A. Upon notification of a CR, assign a number as noted below in accordance with the CR and Stop Work Supporting Information, and enter the CAQ document information in a CAQ tracking log that is maintained to show the status changes of the CR through CR closure.

Each CR is assigned a number for unique identification in the format OSTI-LLNL-XX-Y-ZZZ, where:

- XX = the last two digits of the fiscal year when the CR is initiated.
- Y = D for a Deficiency Report (DR) that is considered to be a non-significant condition, and C for a Corrective Action Report (CAR) that is considered to be a significant condition. A CR is numbered with a D until determined to be significant, at which time the D is changed to a C.
- ZZZ = for DR/CARs, the next sequential number from the CAQ log, beginning with "001" for each fiscal year.

A CAQ tracking log is maintained by the QA Manager (or designee) for tracking the progress and status of CRs. The CAQ log identifies, as a minimum, the unique CR number, brief description, the PI or Responsible Individual responsible for responding and performing corrective actions to the CR, the QA staff member assigned to assess and verify the adequacy of corrective actions taken, the date of issuance, other action due dates as appropriate, and whether a stop work condition was identified.

B. Assign a QA staff member to review the CR. The QA Manager may perform the review.

3.2 QA REVIEW AND ISSUANCE OF A CONDITION ADVERSE TO QUALITY

3.2.1 QA Review (QA Manager or designee):

The purpose of the QA review is to ensure that OSTI-LLNL QA Program requirements for documenting CAQs are met and that adequate information is included to evaluate the condition for significance and the need for a Stop Work Order.

Review the CR documentation and any corrective actions taken during the activity for adequacy (as noted and confirmed in Blocks 7, 7a, and 9) and

document the review by completing Blocks 10 through 12, and Block 1 of the Condition Report (Attachment 1) using the instructions provided. The following actions must be completed within five working days of receipt of the CR (i.e., date of Initiation, Block 8).

A. Verify:

1. The requirement is correctly stated.
2. The condition (noncompliance with the requirement) is clearly described and linked to the requirement.
3. Adequate detail is provided for any investigation or extent of condition research already completed.
4. Adequate detail is provided to determine the significance of the noncompliance, including, if applicable, the recommendation of significance from the PM, Deputy PM or the responsible PI.
5. Adequate detail is provided to determine if a Stop Work Order is required.
6. If the PI or Responsible Individual has already stopped work, a detailed explanation of the basis and scope of the stop work is documented.

B. Work with the Initiator and the appropriate line organization personnel to resolve any inadequacies in the CAQ documentation.

C. If, during the review of the CAQ documentation and requirements, it appears that a CAQ does not exist:

1. Review the CAQ with the Initiator. If the Initiator agrees that a CAQ does not exist, document the basis on the CR Continuation Page (Attachment 2), sign and date it, and obtain the signature and date of the Initiator.
2. Attach the Continuation Page to the CR, and submit the documentation to the QA Manager (or designee) for closure as described in Section 3.8.
3. If the Initiator does not agree, elevate the CR to successively higher levels of management for resolution; document the resolution and obtain the approval of the PM (or designee). Continue processing if the determination is that a CR exists, or if not, process the CR for closure per Section 3.8.

D. For those conditions where Block 7a of the CR has been checked:

1. Confirm that the condition has been satisfactorily corrected as stated.

2. If not in agreement that Block 7a should be checked, line through the check, initial, and date. Notify the PI or Responsible individual that the CR will be processed for issuance per Section 3.2.2.

E. If the Initiator has recommended that the condition be classified as significant (i.e., a CAR that meets the criteria described in Attachment 3), contact the PI or Responsible Individual to confirm the recommendation and then proceed to the next step. Otherwise, evaluate the significance of the condition and the need for a Stop Work Order in accordance with the criteria provided in Attachment 3 and the CR/Stop Work Supporting Information.

1. If the CAQ appears to be significant, notify the PM and the QA Manager (or designee).

2. If a Stop Work Order is recommended, the designee shall immediately contact the QA Manager for initiation of a Stop Work Order in accordance with Section 3.2.2, A. below.

F. Based on the significance determination, check the appropriate DR/CAR box in Block 1 of the CR. Identify the stop work consideration applicability in Block 11.

G. If the condition is not significant but warrants impact, cause, and/or action to prevent recurrence as defined in Section 6.2, check as appropriate in Block 12 of the CR.

H. Forward the CR to the QA Manager (or designee).

3.2.2 QA Manager:

A. Based on the recommendation of the QA staff review, sign Block 13 if in agreement with the recommendation. If not in agreement, initiate revisions and discuss with the parties involved. If a Stop Work Order is recommended, discuss with the PM, and if merited, issue a Stop Work Order as follows:

1. Immediately direct the appropriate PI(s) or Responsible Individual(s) and affected staff to stop work. This direction should include the basis for the Stop Work Order and the scope of work that must be stopped.

2. Provide the PI(s) or Responsible Individual(s) with a memorandum explaining the basis for the Stop Work Order, the scope of work that the Stop Work Order applies to, and the requirements that must be met to remove the Stop Work Order (usually in conjunction with the Project Manager) within two working days.

B. If the CAQ is considered significant, revise the identification number (see Section 3.1.2) and update the CAQ tracking log.

C. Indicate the 30 day response due date (Block 14), and forward the CR to the PI or Responsible Individual (or the PM if the CAQ is a CAR or Stop Work Order) for a response.

3.3 RESPONDING TO A CONDITION REPORT

PI or Responsible Individual (or PM [or Designee] if a CAR or Stop Work Order):

A. Prepare and submit a complete response to the QA Manager within 30 calendar days of the date the CR was issued (as indicated in Block 14) using the CR Response form (Attachment 4). Document the Extent of Condition, check "Yes" or "No" to indicate whether the CAQ is a significant condition or not, and justify (Block 3); describe the impact relative to waste isolation and safety (Block 4); remedial actions required (Block 5); root or apparent cause (Block 6); action to preclude recurrence (Block 7); and due date for completion of corrective action (Block 8) per the instructions provided. Print name, sign and date (Block 9), and submit the response to the QA Manager for evaluation. If necessary, use a CR Response Continuation Page (Attachment 4, Page 3).

B. If the CR identifies an error in a Technical Product (e.g. within a Technical Report, Model Report, technical data), document as part of the corrective action one of the following:

   1. An Errata may be generated using Attachment 5 per the instructions provided.
   2. The Technical/Model Report may be cancelled in accordance with OSTI-LLNL-QIP-6.0, *Document Control*.
   3. Justification may be provided for not generating an Errata and not canceling the Technical Product.

C. For a significant CAQ, perform root cause determination in accordance with established procedures.

D. If a CAQ does not seem to exist, provide a response on a CR Response Continuation Page (Attachment 4, Page 3) and justify the basis for not considering the issue to be a CAQ.

E. If, during CR processing, it is necessary to amend or revise the response, check "amended" in Block 2, and prepare a revised response that completely replaces the previously submitted response (i.e., do not refer to a previous response; resubmit the information).

3.4 EVALUATING A CONDITION REPORT RESPONSE

The purpose of the QA evaluation is to ensure that OSTI-LLNL QA Program requirements for the response are met. The PI or Responsible Individual is responsible for the technical aspects of the response.

QA Manager (or designee):

A. Update the CAQ tracking log to indicate the CR Response was received.

B. Review the response within five working days after notification to ensure the response meets the requirements specified in the instructions for the CR Response.

C. Evaluate the response to determine if a DR should be upgraded to a CAR in accordance with Section 3.2.1, E. To upgrade the DR to a CAR, process the document for reissue in accordance with Section 3.2.

D. If a revision to a response is received prior to review completion, mark the original response "superseded" and destroy. Evaluate only the revised response.

E. Identify the results of the review in accordance with the instructions for the CR Response (Attachment 4).

F. If the response is a continuation page that justifies that a CAQ does not exist, document on that page that the response is accepted or rejected, print name, sign, and date. If accepted, if designee, submit to the QA Manager for CR closure per Section 3.8.

G. If rejected, process response in accordance with Section 3.7.

H. Notify the QA Manager (or designee) and the PI or Responsible Individual of accepted or rejected responses.

I. Update the CAQ tracking log, and maintain a record copy of all associated documentation.

3.5 Completion of Corrective Action

PI or Responsible Individual:

A. Complete the corrective actions as described in the approved response.

B. If unable to meet the due date for completion of corrective action, notify the QA Manager, provide justification and a revised date for completion of actions, where upon the QA Manager (or designee) shall update the CAQ tracking log to reflect the expected completion date and the reasons for the delay.

C. When all corrective actions have been completed, forward documentation to the QA Manager, including:

1. The actual completion date of the corrective action

2. A description of the actual action taken and objective evidence as deemed appropriate to assist in QA verification.

3.6 VERIFICATION OF CORRECTIVE ACTION

QA Manager (or designee):

A. Update the CAQ tracking log.

B. Verify and document the verification of corrective action taken on a CR Continuation Page, identifying the objective evidence reviewed.

C. If the corrective action verification is related to a Stop Work Order, ensure that the documentation is complete and notify the QA Manager (or designee) so that either the partial or complete lifting of the Stop Work Order can be initiated. Submit to the QA Manager (or designee)and PM for approval.

D. Complete the QA Verification actions for the CR in accordance with the instructions provided to indicate corrective action verification/closure.

E. If the actions in the CR Response have been satisfactorily implemented, submit to the QA Manager for approval, processing and CR closure per Section 3.8.

F. If corrective actions are not acceptable:

1. Document specific details of the basis for rejection on a CR Continuation Page.
2. Notify the QA Manager (or designee) of the rejection.

3.7 Processing Unacceptable Responses or Unsatisfactory Corrective Action Implementation

3.7.1 QA Manager:

A. Notify the PI or Responsible Individual in writing of the QA Reviewers basis for rejection and request an amended response within ten working days. Provide copies to the PM and Deputy PM.

B. Update the status of the CAQ tracking log and maintain copies of associated documentation.

3.7.2 PI or Responsible Individual:

A. Prepare an amended response to address the details of the unacceptable response evaluation or unsatisfactory verification results.

B. Process the amended response in accordance with Section 3.3.

3.8 CLOSING A CR

QA Manager:

A. Upon receipt of verification of the satisfactory completion of corrective actions taken (as noted on Attachment 4), approve, or initiate amended actions, as appropriate, and then approve.

B. If it is determined that the CR is not a CAQ, mark N/A in all remaining CR blocks.

C. Update the status of the CAQ tracking log, maintain a record copy of all documentation, and enter the trend code information on the CR.

D. For those CRs that were processed with Block 7a checked (Corrected During Activity) or were not initially considered to be CAQs, submit the completed records package to the Records Coordinator for submittal to the Records Center (RC) per Section 4.0.

E. For those CRs identified as a CAR or associated with a Stop Work Order, submit the documentation to the PM for review and approval. If approved, notify the affected parties regarding the lifting of the Stop Work Order.

F. Notify the PI or Responsible Individual that the CR is closed with copies to the PM and Deputy PM and Initiator (if applicable). Submit the records package per Section 4.0 when all required documents are received.

G. The QA Manager (or designee) shall issue periodic reports regarding the status of open CRs to the PM, Deputy PM and affected PIs/Responsible Individuals.

3.9 TRENDING ANALYSIS AND REPORTING

3.9.1 QA Manager (or designee):

A. Upon receipt of a CR to be trended, identify applicable trend information in accordance with Attachment 6.

B. Enter applicable trend information into a trend database.

C. Periodically (at least annually) review and analyze NCRs and CAQs. Use the Trend Analysis Guidelines summarized in Attachment 6, to identify potential adverse conditions. A potential adverse condition may exist if:

1. Deficiencies identified are of a repetitive nature and the number appears excessive.
2. Recurring deficiencies are of a significant nature.
3. Increases in the number of deficiencies that cannot be easily attributed to increased QA verification activities.

4. Deficiencies are of a programmatic nature, as evidenced by not being limited to a specific Task.
5. Recurring deficiencies appear to be attributable to a single cause or set of conditions.
6. Prepare a CR if a criterion meets the definition of an adverse quality trend.

D. Prepare a Trend Report using Attachment 6, QA Trend Reporting Guidelines.

E. If designated, submit the report to the QA Manager for review.

3.9.2 QA Manager:

A. Review the Trend Report to ensure adverse quality trends have been adequately addressed and the requirements of this procedure are met.

B. Approve the Trend Report and distribute as a minimum to the PM, and Deputy PM, PIs, and QA staff and submit to the RC per Section 4.0.

4. RECORDS

The records listed in Sections 4.1 and 4.2 shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, as individual records or included in a records package, as specified.

4.1 QA RECORDS

Records Package:

Completed CR

Superseded Responses

Completed CR Response

Stop Work Order related correspondence

CR Continuation Pages

Correspondence (including printed electronic mail) transmitting issuance, status, approvals, and closure of CRs

Individual Records:

Trend Reports

4.2 NON-QA LONG-TERM RECORDS

None.

4.3 NON-QA SHORT TERM RECORDS (THREE YEARS OR LESS RETENTION)

QA Tracking Log

5. RESPONSIBILITIES

5.1 The Project Manager (PM) (or designee) is responsible for reviewing CRs, and responding to CAQs identified CARs or that have a Stop Work Order issued, assigning qualified staff to initiate the corrective action, ensuring that actions are adequate and completed in a timely manner, and approving the final closure of CARs or the lifting of Stop Work Orders.

5.2 The QA Manager is responsible for reviewing or designating the review of the adequacy of the CR documentation, approving the recommended disposition, reviewing and approving the adequacy of the response, and reviewing and approving the adequacy of the corrective action; and initiating closure thereof. For CR identified as significant consulting with the affected parties and the PM, and issuing a Stop Work Order if merited. The QA Manager (or designee) is also responsible for trending CRs and NCRs, preparing Trend Reports and periodic CR status reports for management and affected staff, and maintaining a record copy of CR documentation and submitting applicable records to the Record Coordinator for submittal to the RC.

5.3 An Initiator of a CR is responsible for documenting the CR completely per the requirements of this procedure and concurring if it is further determined that a CR does not exist.

5.4 The Principle Investigator (PI) or Responsible Individual is responsible for cooperating with the CR Initiator, providing technical input and a recommendation as to the CR significance, for preparing a complete response, ensuring adequate corrective actions are implemented, and notifying the QA Manager upon completion thereof.

6. ACRONYMS AND DEFINITIONS

6.1 ACRONYMS

CAQ	Condition Adverse to Quality
CAR	Corrective Action Report
CR	Condition Report
DOE	U.S. Department of Energy
DR	Deficiency Report
LLNL	Lawrence Livermore National Laboratory
NCR	Nonconformance Report
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
OQA	Office of Quality Assurance

PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements and Description

6.2 DEFINITIONS

Cause: The cause that is most likely the cause of the adverse condition based on readily available information.

Condition Adverse to Quality (CAQ): A state of noncompliance with QA program requirements.

Condition Report (CR): A document used to report a CAQ and classify the condition as a DR or, if the CAQ is significant, as a CAR.

Corrective Action: A measure taken to rectify a CAQ and, where necessary, to preclude recurrence.

- Immediate Corrective Actions–Those actions taken at the time the CAQ is identified to mitigate the consequences of the CAQ and bring the process under control (immediate actions to prevent recurrence).
- Remedial Actions–Those actions taken to correct specifically identified CAQs and those actions taken to allow work to continue.
- Corrective Actions to Prevent Recurrence–Those actions taken to address the root cause(s) of the CAQ.

Errata: Any error, discrepancy or inconsistency noted in a document.

Extent of Condition: The determination whether the identified condition impacts other facilities, units, system, components, documents, organizations, etc. The level of detail of this determination should be commensurate with the significance of the condition.

Impact: The determination if the identified condition has an affect on waste isolation, safety, and/or to other work, if any.

Nonconformance Report (NCR): A form used for reporting nonconforming conditions of items or samples.

Root Cause: The identified cause of a CAQ that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar CAQ.

Significant CAQ: A CAQ which, if uncorrected, could have a serious effect on safety or the ability to isolate waste. A significant CAQ should meet the criteria established in Attachment 3, CR and Stop Work Supporting Information.

Stop Work Order: A formal directive issued by QA management that work must be stopped until resolution of the related significant CAQ.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-15.0, *Nonconformances*

OSTI-LLNL-QIP-17.0, *Records Management*

8. ATTACHMENTS

Attachment 1 - Condition Report
Attachment 2 - Condition Report Continuation Page
Attachment 3 - CR and Stop Work Supporting Information
Attachment 4 - Condition Report Response
Attachment 5 - Errata
Attachment 6 - QA Trend Analysis Guidelines

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0

Initial issue.

10. APPROVALS

Preparer: Leigh Gouveia — Date: 2/25/05

Technical Reviewer: QINHONG HU — Date: 2/25/05

QA Reviewer: VICTOR J. BARISH JR — Date: 2/25/05

Project Manager: DAVID B. McCALLEN — Date: 2/25/05

Lawrence Livermore National Laboratory	*CONDITION REPORT*	1. ☐ DR ☐ CAR CR NO: Page of QA: QA

2. Controlling Document (Document Identifier, Rev./Mod.Number, and/or effective date):	3. Related Report No (if applicable):
4. Principal Investigator (PI) or Responsible Individual:	5. Discussed With:
6. Requirement:	
7. Description of Condition:	7a. ☐ Corrected During Activity (Describe all actions taken to close in Block 7)
8. Initiator: Printed Name Signature Date	9. PI or Responsible Individual: (Required if 7a is checked) Printed Name Signature Date
10. QA Review (QA Manager or designee): Printed Name Signature Date	11. Does a stop work condition exist? ☐Yes ☐ No 12. For a DR, check if Response must have: ☐ Impact ☐Cause ☐ Action to Prevent Recurrence
13. QA Concurrence/Issuance (QA Manager): Printed Name Signature Date	14. Due Date (30 calendar days after issue): Date:_____
15. QA Corrective Action Approval (QA Manager) Printed Name Signature Date	16 Trend Information
17. For CARs or Stop work Orders only: Project Manager Signature Date	

CR INSTRUCTIONS

The numbered steps represent the numbered blocks on the CR. Complete only the applicable information. Mark blocks that are not applicable "N/A." Use the CR Continuation Page or reference attachments if additional space is required.

Initiator:

2. Enter the document identifier number, revision/modification number, and/or effective date of the document that identifies the requirement(s).

3. Enter the number of the report that resulted in identifying the CAQ (e.g., Audit Report Number or Surveillance Report Number). Enter "N/A" if there is not a related report.

4. Enter the Principal Investigator (PI) or Responsible Individual responsible for the activity or process in which the CAQ occurred.

5. Enter the name of the individual(s) with whom the condition was discussed. The condition shall be discussed with individuals from the line organization responsible for the activity and the QA Manager (or designee).

6. State the requirement from the controlling document, including the specific reference (paragraph/section number) to the controlling document.

7. Provide the following:

   a) Describe the condition found in concise, narrative form, including references to examples discovered.

   b) Ensure that the description provides a clear link to the requirement that provides the basis for the condition.

   c) Provide adequate detail to enable the determination of the significance of the condition. If provided, include a recommendation from the line organization of the significance of the condition (i.e., whether the condition is a DR or a CAR condition per Attachment 3 and the CR and Stop Work Supporting Information).

   d) Provide adequate detail to enable the determination of the need for a Stop Work Order.

   e) Describe any actions taken as a result of identification of the condition (both immediate corrective actions and remedial actions).

   f) If work has been stopped by the line organization as a result of the discovery of the condition, clearly state this in the description of condition, including the scope of the work that has been stopped.

   g) For a Corrected During Activity condition, include the specific remedial actions taken during the activity and the Initiator's perspective that the condition is isolated and requires no further extent of condition investigation.

7a. Check this box only if all necessary remedial actions have been completed and the condition appears to be isolated with no further extent of condition warranted.

8. Print name, sign, and date the CR.

9. Obtain the PI or Responsible Individual's signature and date for a condition corrected during an activity (i.e., Block 7a is checked).

Upon completion of Steps 2 through 9, submit to the QA Manager.

QA Manager (or Designee)

10. Review the CR for adequacy.

11. Determine if a stop work condition exists based on criteria in Attachment 3, and indicate this by checking "Yes" or "No".

12. Determine if the response must have Impact, Cause, and Action to Prevent Recurrence.

1. Based on the significance determination; Check the appropriate DR/CAR.

QA Manager

13. Review the Initiator and QA Review documentation; make revisions to the CR as necessary prior to approval and issuance of the CR. If a Stop Work Order is recommended, consult with the Project Manager (PM) and affected PI/Responsible Individual. If merited, initiate a Stop Work Order per Section 3.3.2 of this procedure.

14. Indicate the due date of 30 calendar days after issuance (date indicated in Block 13)., and submit to the PI or Responsible Individual for a response and initiation of corrective actions, as appropriate.

QA Manager

15. Upon receipt of a response for which the corrective action has been verified and accepted as adequate (Attachment 4), review the action taken and associated documentation; indicate acceptance of the response and corrective actions taken to a DR/CAR, or Stop Work Order by printing name, signing, and date.

16. Indicate trending information based on guidelines provided in Attachment 6. If a CAR or Stop Work Order issues, submit the CR and associated documentation to the PM for approval.

Project Manager

17. If satisfied with the actions taken to CAR and/or Stop Work Order, sign and date, or initiate further actions prior to approval.

Lawrence Livermore National Laboratory	***CONDITION REPORT CONTINUATION PAGE***	CR NO: Page of QA: QA

CR AND STOP WORK SUPPORTING INFORMATION

1.0 CRITERIA FOR EVALUATION

The following criteria are used to evaluate the significance of identified CAQs documented on a CR.

1.1 DR (condition adverse to quality)

A DR is a CAQ that does not meet the criteria for a significant CAQ. A non-significant CAQ is documented as a DR on the CR.

1.2 CAR (significant condition adverse to quality)

A CAQ is significant if it meets one or more of the following criteria:

A. The CAQ indicates a significant failure or breakdown in the implementation of QA program requirements.

B. The CAQ was evaluated and determined to have a major impact on cost and/or schedule (e.g., project milestones, significant impact on products, and/or unacceptable costs).

C. Repeated attempts to resolve the CAQ have been unsuccessful.

D. Repetitive conditions that when taken collectively:

1. Indicate a programmatic failure to properly implement the QA program
2. May be precursors for a significant technical deficiency or problem
3. May significantly reduce the margin of safety.

E An significant adverse quality trend exists as identified in Section 3.9 of this procedure.

F. A CAQ is identified in items or activities important to safety or waste isolation that compromises the ability to prevent or mitigate the consequences of an accident, and presents a significant hazard to the safety and health of workers and/or the public.

2.0 DETERMINING STOP WORK CONDITIONS

A stop work condition exists when continuing work would cause one or more of the following:

A. The quality of scientific investigation results is irreparably compromised.

B. An item does not function as intended due to a CAQ in the processing, installation, modification, or operation.

C. A significant hazard is presented to the health or safety of workers and/or the public.

D. A significant breakdown or failure in the implementation of QA program requirements compromises the quality of items or activities important to safety or waste isolation.

Lawrence Livermore National Laboratory	**2. Submittal Page of** ☐ Amended *CONDITION REPORT RESPONSE*	1. ☐ DR ☐ CAR CR NO: Page of QA: QA

3. Extent of Condition Significant: ☐ Yes ☐ No

4. Impact: (Provide an impact statement relative to waste isolation, safety, or impact to other work, if any.)

5. Remedial Actions Required:

6. ☐ Root Cause (For a significant CAQ, attach results of formal root cause determination)
☐ Apparent Cause

7. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring.)

8. Due Date for Completion of Corrective Action:	9. Principal Investigator or Responsible Individual Printed Name Signature Date

10. QA Corrective Action Verification/Closure

☐ Accept ☐ Reject _____

QA Manager (or designee): Printed Name Signature Date

CR RESPONSE INSTRUCTIONS

The numbered steps represent the numbered blocks on the CR Response. Complete only the applicable information. Mark blocks that are not applicable "N/A." Use the CR Response Continuation Page or reference attachments if additional space is required.

Principal Investigator (PI) or Responsible Individual:

If a CAQ does not seem to exist, provide a response on a CR Response Continuation Page and justify the basis for not considering the issue to be a CAQ.

1. Enter the applicable CR number. Do not place page numbers in this block as this will be used by the QA Manager (or designee) when preparing the final records package..

2. If deemed necessary to number the submittal pages, enter the submittal page count in the upper section of this block. If the specific submittal is an amended response, check this box.

3. Document the extent of condition investigation activities and include a detailed listing of those items or documents that are found to be part of the extent of condition. If an extent of condition investigation is not warranted, provide justification. For a DR, check the appropriate significance box to represent the PI or Responsible Individual's assessment.

4. Identify the impact relative to waste isolation, safety, and/or to other work, if any. If there is no impact, then provide justification or rationale as to why there is no impact. Otherwise, mark block N/A if impact statement is not required.

5. A. Provide specific remedial actions that have been or will be taken to address each specific type of condition noted in Block 3.

   B. Include the immediate corrective action taken if not reported on the description of condition to allow work to continue or to mitigate the consequences of the CAQ.

   C. List specific actions in a concise bulleted or numbered format. Actions stated must be verifiable.

   D. Provide names of specific individuals responsible for completing each action and the expected completion date, to facilitate closure verification activities.

   E. If remedial actions are deemed unnecessary or cannot be taken, then provide a clear justification or rationale as to why no actions were taken.

6. For a significant CAQ, perform a root cause determination (in accordance with a procedure to be developed, and attach it to the response). Provide the apparent cause if the "Cause" box of Block 13 of the CR is checked.

7. Identify those actions to be taken to preclude recurrence of the specific causes identified in Block 6. Actions planned should stem directly from the cause statements. These actions must be verifiable prior to closure of the CR. (This is required if the "Action to Prevent Recurrence" box of Block 12 of the CR [Attachment 1) is checked, or for a CAR.)

8. Provide the due date for completion of all the corrective actions outlined in the response.

9. Print name, sign, and date.

QA Manager (or Designee)

10. Review the CR Response and associated corrective action documentation and indicate acceptance or rejection, provide the bases for acceptance or rejection on the CR Response Continuation Page, print name, sign, and date. If designee, submit to verified CR Response to the QA Manager for concurrence (which will be document In Block 15 of the CR (Attachment 1).

Lawrence Livermore National Laboratory	***CONDITION REPORT RESPONSE CONTINUATION PAGE***	CR NO: Page of QA: QA

Lawrence Livermore National Laboratory	**ERRATA**	2. QA: 3. Page of

1. Condition Report No.	4. Product DI: _____
5. Title: _____	6. Revision _____
7. Description of Error:	8. Clarification/ Restriction

EXAMPLE

9. Principle Investigator/Author (Print Name)	Initials	Date

Instructions for Errata

Principal Investigator/Author

1. Enter Condition Report number.
2. Input QA designator.
3. Input current page number and total number of pages.
4. Identify Product DI/DTN.
5. Identify the Title of the Product.
6. Identify the revision and change number(s), if applicable.
7. Describe the error(s), including its location (page or section).
8. Describe the clarification or restriction for use, as appropriate, and identify affected Data Tracking Numbers (DTN).
9. Print or type name, initials and date.

Additional requirements:

Principal Investigator/Author

- **IF** the identified error concerns data,

  THEN forward a copy of the completed Errata to the Technical Data Coordinator for processing per OSTI-LLNL-QIP-SIII.3.

- **IF** the error could adversely affect other Technical Products,

  THEN initiate an impact review in accordance with OSTI-LLNL-QIP-SIII.3.

- **Forward** the completed Errata to Records Coordinator for submittal to the RC in accordance with OSTI-LLNL-QIP-17.0.

QA TREND ANALYSIS GUIDELINES

Review and analyze the NCR and CAQ Logs for indications of quality trends in items and conditions adverse to quality.

Item-Related Trends – NCRs, should be examined for recurrence or similarities in the following subject areas:

A. Item type
B. Deficiency
C. Deficiency cause
D. Task

Conditions Adverse to Quality (CAQ) Trends (DRs, CARs) - Examine for recurrence of similarities in the following subject areas:

A. Deficiency
B. Deficiency cause
C. Task

TREND REPORTING GUIDELINES

The Trend Report is intended to report on adverse trends identified through the NCR reporting process described in OSTI-LLNL-QIP-15.0, *Nonconformances*, and the CAQ reporting process described in this procedure to identify additional adverse and positive quality trends discovered as a result of the periodic evaluation of deficiencies. As such, the Trend Report is formatted to give management a brief overview of the quality program status, followed by sufficient details to support the conclusions.

The Trend Report shall contain, at a minimum:

A. An Executive Summary identifying:

1. Conclusions reached regarding trends in programmatic deficiencies, hardware deficiencies, and corrective action effectiveness.
2. Status of previously identified trends, if any
3. New positive trends, if any
4. New adverse trends, if any

B Specific results of trend analyses describing:

1. Trend identification, if any
2. Deficiencies, if any, which are programmatic and not limited to a specific task
3. As applicable, status of previously identified trends, new trends resulting in NCRs, positive trends, overall conclusions regarding the effectiveness of QA Program implementation

C. Figures, as appropriate, that provides a visual display of trend data discussed in the report.